

Amendments to the Specification

Please replace the paragraph beginning at page 6, line 14, with the following rewritten paragraph:

-- Referring to Fig. 1, a system 10 for establishing vascular access according to the principles of the present invention comprises a radially expandable sleeve 12, a dilator 14, and a guidewire 16. The radially expandable sleeve comprises a radially expandable tubular body having a proximal end, a distal end, and an axial lumen extending from the proximal end to the distal end. Usually, a handle 20 is provided at the proximal end of the body so that the sleeve can be manually held during use, e.g., tension can be applied on the handle as the dilator 14 is passed through the body of the sleeve as described in more detail below. The radially expandable sleeve 12 may have a compliant or elastic structure which permits expansion from an initial small diameter (radially collapsed) configuration to a larger diameter configuration which is caused by introduction of the dilation therethrough. Use of the compliant or elastic sleeve will require a separate component for maintaining the expanded diameter of the tissue tract, as described in more detail below. Alternatively, the radially expandable sleeve can have a plastic or other locking structure so that, once expanded, it will retain its larger diameter configuration without the need for using other supports, devices, or the like. For example, as seen in FIG. 1, the locking structure may include a tether 15 which may be fixedly secured to the distal end of radially expandable sleeve 12 and extending axially through radially expandable sleeve 12. Accordingly, in use, following radial expansion of sleeve 12, tether 15 may be tightened and a proximal end of tether 15 secured to handle 20. In this manner, axial elongation and in turn radial constriction of sleeve 12 is prevented until the proximal end of tether 15 is released.

Please replace the paragraph beginning at page 7, line 8, with the following rewritten paragraph:

-- A dilator 14 may be a simple dilator having a tapered distal end and smooth transition to a uniform body diameter. The dilator will have a guidewire lumen to permit introduction over the guidewire and through the radially expandable sleeve, as described in more detail below. As illustrated, dilator 14 is in the form of a conventional sheath/dilator assembly of the type which is commercially available from vendors, such as Bard Cardiology, Billerica, Massachusetts, under the trade name InputTM. The dilator/sheath assembly includes an outer sheath 30 with an inner tapered dilator 32 which is removable from the sheath. The sheath has a hemostatic valve [[34]] 36 at its [[distal]] proximal end and a side access tube [[36]] 37 which permits perfusion or aspiration through the lumen of the sheath. The inner tapered dilator 32 has a handle 38 at its proximal end and an internal lumen which permits introduction over the guidewire 16.--

Please replace the paragraph beginning at page 8, line 20, with the following rewritten paragraph:

-- Referring now to Figs. 4A-4C, use of the assembly of Fig. 3 for dilating the tissue tract to a blood vessel BV, typically using a needle as described above in connection in Fig. [[3A]] 2A. Usually, the guidewire 54 used for more difficult introductions will have a slightly smaller diameter than would otherwise be necessary, such as a diameter of about 0.6 mm (0.025 in.). The assembly of the sleeve introducer 50 and radially expandable sleeve 52 is then introduced over the guidewire, with the guidewire passing directly through the lumen of the introducer 50. The tapered distal end 60 of the introducer 50 thus leads the way through the tissue over the guidewire 54, so that the taper facilitates passage of the assembly through the tissue. After the

assembly is in place, as shown in Fig. 4B, a dilator ~~[[14]]~~ 30 having an inner portion 32 may be introduced directly over the exterior of the sleeve introducer 50, as shown in FIG. 4C. After the tissue tract has been completely dilated, the combination of the sleeve introducer 50 and guidewire 54 may be withdrawn, leaving the inner diameter of the inner dilator portion 32 available for expanded access to the blood vessel BV. --

Please replace the paragraph beginning at page 9, line 1, with the following rewritten paragraph:

-- Referring now to Fig. ~~[[3]]~~ 5, kits according to the present invention will comprise at least a radially expandable sleeve 12 together with instruction for use IFU setting forth a method according to the principles of the present invention. Usually, a dilator 14' will also be included in the kit. The dilator 14' is shown as a simple dilator without an associated access sheath. Such a dilator is suitable for use with a plastically deformable radially expandable sleeve. The kits may optionally further comprise a guidewire GW, a sleeve introducer 50, and/or a needle N and all kit components will typically be packaged together in a box, tray, tube, pouch, or other conventional medical device package P. The kit components which are employed in the medical procedure will typically be maintained within sterile packaging, with individual components being packaged in separate sterile containers, all components of the kit will be placed together within a common package. The instructions for use may be provided on a separate printed sheet, such as a conventional package insert, or may be printed in whole or in part on other portions of the packaging or the device itself. --